Appl. No. : **10/090,038**
Filed : **February 27, 2002**

SUMMARY OF INTERVIEW

Identification of Claims Discussed

On February 22, 2005, Examiner Choi left a voicemail for the undersigned, Ned A. Israelsen regarding Claims 1, 38-54.

Proposed Amendments

Examiner Choi proposed adding the limitation l mitation "wherein said synergistically effective dose is sufficient to raise serum HDL cholesterol levels," to Claims 1, and 8-54.

Results of Interview

Examiner Choi indicated that Claims 1, and 8-54 were patentable, provided the claims were amended to further recite the limitation "wherein said synergistically effective dose is sufficient to raise serum HDL levels."

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REMARKS

Applicants have canceled Claims 1-6 and 8-37, without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claims in this or any other patent application.

Applicants have amended Claims 7 and 38 to recite "wherein said synergistically effective dose is sufficient to raise serum HDL cholesterol levels." Applicants submit that no new matter has been added by the amendments, and that support for the amendments can be found throughout the specification, for example in Figures 2 and 14. Applicants have amended Claims 50-52 such that they are in independent form.

Claims 7 and 38-54 are presented for examination.

Claim Objections

The Examiner has objected to Claims 16-18, and 50-52 as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Examiner states that nicotinic acid and picolinic acid are bioactive, such that the phrase "consisting essentially of" would exclude nicotinic acid and picolinic acid.

Applicants have amended Claims 50-52 to be in independent form. In view of the amendments, Applicants request that the Examiner withdraw the objection to Claims 50-52.

Rejection Under 35 U.S.C. § 102(b) – Anticipation

The Examiner has maintained the rejection of Claims 1, 4-6, 8, 10-13, and 19 as being anticipated by or in the alternative unpatentably obvious over Rath (U.S. Patent No. 6,693,129). The Examiner also maintained the rejection of Claims 1-5, 8-13, 19, 20 23-28, 30, and 31-37 as being anticipated by or in the alternative obvious over Jensen (U.S. Patent No. 5,194,615). Applicants have canceled the above claims, thereby obviating the Examiner's rejection.

Rejection Under 35 U.S.C. 103(a) – Obviousness

The Examiner has rejected Claims 1-20 and 23-54 as being unpatentably obvious over McCarty (U.S. Patent No. 5,789,401, hereinafter the "'401 Patent"), or McCarty (U.S. Patent No. 5,929,066, hereinafter the "'066 Patent"), in view of de al Harpe et al. (U.S. Patent No.

5,948,772, hereinafter the "'772 Patent"), Jensen (U.S. Patent No. 5,194,615, hereinafter the"'615 Patent"), Brand-Miller ((1994) Am. J. Clin. Nutr.), Reddi ((1988), Life Sciences), McCarty ((1999), Med. Hypotheses), Boyle ((1977), Southern Med. J.), Mossop ((1991), Central African J. Med.), Dokusova ((1972), Kardiologiia), and McCleary (U.S. Patent No. 6,579,866). The Examiner maintains that the '401 patent teaches a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of chromic tripicolinate to biotin is between 100:1 and 5:1, for reducing hyperglycemia and stabilizing blood glucose levels. The Examiner maintains that the '066 patent teaches a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 2:1 and 1:200 (w/w), for reducing hyperglycemia and stabilizing the level of serum glucose, wherein the amount is selected to provide a synergistic effect. According to the Examiner, de la Harpe teaches that chromium supplements reduce hyperglycemia, stabilize serum glucose and control serum lipid levels, and that nicotinic acid and/or picolinic acid facilitates that absorption of chromium. The Examiner asserts that Jensen teaches that chromium nicotinate is effective in reducing triglycerides. The Examiner also asserts that Brand-Miller teaches ranking foods based on their glycemic index results in measurable clinical gains. According to the Examiner, Reddi teaches that biotin lowers post-prandial glucose levels and improves tolerance to glucose and decreases insulin resistance, and McCarty (1999) teaches the combination of biotin and chromium picolinate to treat insulin resistance, enhance postprandial glucose uptake, and inhibit excessive hepatic glucose production. The Examiner maintains that Boyle teaches that natural sugars and grains have high concentrations of chromium, and that most of this is removed during the refining process. The Examiner also maintains that Mossop teaches that individuals who eat unrefined maize have lower fasting blood glucose levels than do individuals who eat refined cereals. According to the Examiner, Dokusuva teaches that biotin reduces levels of cholesterol in patients with atherosclerosis and hyperlipidemia, and McCleary teaches treating insulin resistance, hyperinuslinemia, hypertriglyceridemia, low HDL syndrome, small dense LDL syndrome and postprandial hyperlipidemia by administering a composition containing biotin and chromium picolinate.

Per the Examiner's suggestion on February 22, 2005, Applicants have amended Claims 7 and 37-54 to recite the limitation "wherein said synergistically effective dose is sufficient to raise

serum HDL cholesterol levels." Therefore, Applicants request that the Examiner reconsider and withdraw the rejection of Claims 7, and 38-54, consistent with the telephonic interview.

CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE MARTENS, OLSON & BEAR, LLP

Dated: 5-24-05

By: _____

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